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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/010,065      | 12/05/2001  | Keith D. Allen       | R-648               | 2751             |

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[REDACTED] EXAMINER

BERTOGLIO, VALERIE E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1632     | 9            |

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                             |                        |                     |
|-----------------------------|------------------------|---------------------|
| <b>Offic Action Summary</b> | <b>Application N .</b> | <b>Applicant(s)</b> |
|                             | 10/010,065             | ALLEN ET AL.        |
|                             | <b>Examiner</b>        | <b>Art Unit</b>     |
|                             | Valarie Bertoglio      | 1632                |

- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disp sition of Claims

- 4) Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-56 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
  - 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                               |                                                                             |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input checked="" type="checkbox"/> Other: <i>Election/Restriction</i> . |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a nucleic acid construct and methods of making the construct, classified in class 536, subclass 23.1.
- II. Claims 5-7, 10, 34, drawn to cells with a disruption in a glucagon receptor gene, classified in class 435, subclass 325.
- III. Claims 9, 18-33, drawn to a transgenic animal comprising a disruption in a glucagon receptor gene, classified in class 800, subclass 13.
- IV. Claims 12,13,36,37, drawn to methods of using a transgenic animal comprising a disruption in a glucagon receptor gene to test agents, classified in class 800, subclass 3.
- V. Claims 11 and 35, drawn to a method of making a transgenic animal, classified in class 800, subclass 21.
- VI. Claims 14-16,38,39, drawn to methods of using cells with a disruption in a glucagon receptor gene to test agents, classified in class 435, subclass 325.
- VII. Claims 17, 40 and 41, drawn to an agent, classified in class 530, subclass 350.
- VIII. Claims 43 and 54, drawn to a method of treating obesity, classified in various classes and subclasses

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- IX. Claims 43 and 55, drawn to a method of treating a diabetic condition, classified in various classes and subclasses
- X. Claims 44-47, 49,50,52,53 drawn to a method of identifying an agent that inhibits the activity or function of glucagon receptor by contacting the agent to a cell that expresses the glucagon receptor gene, and the agent, classified in class 530, subclass 350.
- XI. Claims 48 and 51 drawn to a method of identifying an agent that has an effect on obesity using a mouse expressing a glucagon receptor gene, classified in class 530, subclass 350.
- XII. Claim 56, drawn to a database, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the nucleic acid construct can be used as a probe while the cells can be used in in vitro assays to determine agents that modulate glucagon receptor expression. Furthermore, the protocols and reagents required for the nucleic acid and the cells are materially distinct and separate. The burden required to search the nucleic acid construct and the cells together, each having materially different structures, would be undue.

Inventions I and III are patentably distinct because, the nucleic acid construct can be used as a probe while the transgenics can be used in in vivo assays to determine agents that modulate glucagon receptor expression. The burden required to search the

nucleic acid construct and the transgenic together, each having materially different structures, would be undue.

Inventions I and IV are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vivo* assays to determine agents that modulate glucagon receptor expression. The protocols and reagents required for the nucleic acid and using the transgenics are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the methods together would be undue.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid construct can be used as a DNA probe.

Inventions I and VI are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vitro* assays to determine agents that modulate glucagon receptor expression. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the method together would be undue.

Inventions I and VII are patentably distinct because, the nucleic acid construct can be used as a probe while the agent can be used to modulate glucagon receptor expression. The protocols and reagents required for the nucleic acid and the agent are materially distinct and separate. The construct does not require the agent and the agent does not require the construct. Furthermore, the burden required to search the nucleic acid construct and the agent together, each having materially different structures, would be undue.

Inventions I and VIII are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used to treat obesity. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the methods together would be undue.

Inventions I and IX are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used to treat a diabetic condition. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the methods together would be undue.

Inventions I and X are patentably distinct because, the nucleic acid construct can be used as a probe while the methods can be used in *in vitro* assays to determine agents that inhibits glucagon receptor activity or function. The protocols and reagents

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required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the method together would be undue.

Inventions I and XI are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vitro* assays to determine agents that affect obesity. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the method together would be undue.

Inventions I and XII are patentably distinct because the nucleic acid construct can be used as a probe while the database of Invention XII can be used for statistical analysis. The nucleic acid construct is not necessary for the database nor is the database necessary for the nucleic acid construct. The burden required to search Inventions II and XII together would be undue.

Inventions II and III are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the transgenics can be used in *in vivo* assays to determine agents that modulate glucagon receptor expression. Furthermore, the protocols and reagents required for the cells and the transgenics are materially distinct and separate. The burden required to search the cells and the transgenic together, each having materially different structures, would be undue.

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Inventions II and IV are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the method can be used in *in vivo* assays to determine agents that modulate glucagon receptor expression. The protocols and reagents required for the cells and methods of using the transgenic are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. Furthermore, the burden required to search the cells and the method of using a transgenic together would be undue.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells can be used for *in vitro* assays to determine agents that modulate glucagon receptor expression.

Inventions II and VI are related as product and process of use. In the instant case the method of testing agents can be done *in vivo* using transgenics comprising a disruption in the glucagon receptor while the cells can be used in *in vitro* assays to determine differential gene expression between cells with a disruption in glucagon receptor and wild type cells.

Inventions II and VII are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the agent can be used to modulate glucagon receptor expression. The cells do not require the agent and the

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agent does not require the cells. Furthermore, the burden required to search the cells and the agent, each having materially different structures, would be undue.

Inventions II and VIII are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the method can be used to treat obesity. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. Furthermore, the burden required to search the cells and the methods together would be undue.

Inventions II and IX are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the method can be used to treat a diabetic condition. The protocols and reagents required for cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. Furthermore, the burden required to search the cells and the methods together would be undue.

Inventions II and X are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the methods can be used in *in vitro* assays to determine agents that inhibits glucagon receptor activity or function. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the construct. Furthermore, the burden required to search the cells and the methods together would be undue.

Inventions II and XI are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the method can be used in *in vitro* assays to determine agents that affect obesity. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. Furthermore, the burden required to search the cells and the method together would be undue.

Inventions II and XII are patentably distinct because the cells of Invention II can be used to isolate protein while the database of Invention XII can be used for statistical analysis. The cells are not necessary for the database nor is the database necessary for the cells. The burden required to search Invention II and XII together would be undue.

Inventions III and IV are related as product and process of use. In the instant case the method of testing agents can be done *in vitro* using cells comprising a disruption in glucagon receptor. Furthermore, the transgenic can be used to determine the role of glucagon receptor *in vivo*.

Inventions III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the transgenic can be made by injecting the blastocyst with DNA.

Inventions III and VI are patentably distinct because the transgenic can be used to determine the role of glucagon receptor *in vivo* while methods of using the cells are to

identify agents *in vitro*. Furthermore, the protocols and reagents required for the transgenics and the methods are materially distinct and separate. The burden required to search the transgenic and the methods of using cells together, each having materially different structures, would be undue.

Inventions III and VII are patentably distinct because the transgenic can be used to determine the role of glucagon receptor *in vivo* while the agent is used to modulate glucagon receptor. The protocols and reagents required for the transgenics and the agent are distinct and separate. The burden required to search the transgenic and the agent together, each having materially different structures, would be undue.

Invention III and Inventions VIII and IX are patentably distinct because the transgenic can be used to determine the role of glucagon receptor *in vivo* while the method can be used to treat obesity (Invention VIII) or a diabetic condition (Invention IX). The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. Furthermore, the burden required to search the transgenic and the methods together would be undue.

Inventions III and X are patentably distinct because the transgenic animal can be used to determine the role of glucagon receptor *in vivo* while the methods can be used to identify agents that inhibit glucagon receptor function. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic.

Furthermore, the burden required to search the transgenic and the methods together would be undue.

Inventions III and XI are patentably distinct because the transgenic animal can be used to determine the role of glucagon receptor in vivo while the methods can be used to identify agents that inhibit glucagon receptor function. The animals of Inventions III and XI are materially distinct. The transgenic of Invention III has a disruption of the glucagon receptor gene. The mouse of Invention XI necessarily comprises a functional glucagon receptor gene. The transgenic does not require the methods and the methods do not require the transgenic. Furthermore, the burden required to search the transgenic and the methods together would be undue.

Inventions III and XII are patentably distinct because the transgenic animal can be used to determine the role of glucagon receptor in vivo while the database of Invention XII can be used for statistical analysis. The transgenic is not necessary for the database nor is the database necessary for the transgenic. The burden required to search Invention III and XII together would be undue.

The methods of each of inventions IV-VI, VIII-XI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The purpose of Inventions IV-VI and VIII-XI is different. The transgenic used in Invention IV is not required for the methods of Inventions V, VI or VIII-XI. The cells of Invention VI are not necessary for Inventions IV, V, VIII-XI. The burden required to search Inventions IV-VI and VIII-XI together would be undue.

Inventions IV and VII are patentably distinct because, the agent can be identified from in vitro assays using cells harboring a disruption in glucagon receptor. The agent does not require the methods of using the transgenic and the methods do not require the agent. Furthermore, the burden required to search the transgenic and the agent, each having materially different structures, would be undue.

Inventions IV, V, VI, or VIII-XI and Invention XII are patentably distinct because the methods of Inventions IV, V, or VI or VIII-XI do not require the database of Invention XII and the database does not require the methods. The burden required to search inventions IV, V, VI or VIII-XI and Invention XII together would be undue.

Inventions V and VII are patentably distinct because, the method can be used to generate a transgenic animal while the agent can be used to modulate glucagon receptor expression. The protocols and reagents required for the transgenic and the agent are materially distinct and separate. The transgenic does not require the agent and the agent does not require the construct. Furthermore, the burden required to search the transgenic and the agent, each having materially different structures, would be undue.

Inventions VI and VII are patentably distinct because, the methods can be used to identify agents in vitro while the agent can be used to modulate glucagon receptor function in vivo. The methods do not require the agent and the agent does not require the methods. Furthermore, the burden required to search the agent and the methods would be undue.

Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agent can be used to modulate glucagon receptor gene function in vitro.

Inventions VII and IX are related as product and process of use. In the instant case the agent can be used to modulate glucagon receptor gene function in vitro .

Inventions VII and X are patentably distinct because the agent can be used to modulate glucagon receptor function in vivo while the methods can be used to identify agents that inhibit glucagon receptor function in vitro. The protocols and reagents required for the agent and the methods are materially distinct and separate. The agent does not require the methods and the methods do not require the agent. Furthermore, the burden required to search the agent and the methods together would be undue.

Inventions VII and XI are patentably distinct because the agent can be used to modulate glucagon receptor function in vivo while the methods can be used to identify agents that affect obesity. The protocols and reagents required for the agent and the methods are materially distinct and separate. The agent does not require the methods and the methods do not require the agent. Furthermore, the burden required to search the agent and the methods together would be undue.

Inventions VII and XII are patentably distinct because the agent can be used to modulate gene expression or gene product activity while the database of Invention XII0

can be used for statistical analysis. The agent is not necessary for the database nor is the database necessary for the agent. The burden required to search Inventions VII and XII together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

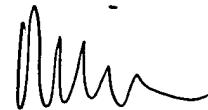
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Valarie Bertoglio  
Patent Examiner



MICHAEL C. WILSON  
PATENT EXAMINER